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K051827

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510(k) SUMMARY

THESSYS MULTISCOPE
510(k) Notification #K051827

1. Submitter Information

Manufacturer: Joimax GmbH
RaumFabrik 33a
Amalienbadstrasse
76227 Karlsruhe – Germany

Establishment Registration Number: 3005083075

Contact Person: Mathias Notheis, Project Manager
Telephone: +49 721-25514-511
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Date Prepared: 9 August 2005

2. Device Identification

Proprietary Name(s): THESSYS MULTISCOPE

Classification Name:	Arthroscope
Classification Regulation No.:	21 CFR § 888.1100
Classification:	Class II
Product Code:	HRX

3. Predicate Device(s)

Endius Spine Endoscope
Richard Wolf Discoscope with Panoview Plus Optics
Richard Wolf Yeung Endoscopic Spine System (YESS)
Pollux Arthroscope

4. Device Description

A multi-channel endoscope having working channel and/or irrigation channel(s), used to visualize the operative site.

5. Intended Use

The THESSYS MULTISCOPE is intended to visualize the inside of the patient through a cannulated incision for diagnostic and surgical procedures, such as arthroplasty, nucleotomy, discectomy, and foraminotomy.

6. Contraindications

There are no known contraindications directly related to the device. The attending physician must determine the appropriateness of the application while considering the general condition of the patient.

7. Technological Characteristics

The THESSYS MULTISCOPE consists of light transmitting optical fibers and an image transmitting fiber bundle and lens, or a rigid rod-lens transmitting images. It has one or two irrigation channels and a working channel contained within a rigid stainless steel envelope.

8. Substantial Equivalence Determination

The THESSYS MULTISCOPE is substantially equivalent to the Richard Wolf Discoscope with Panoview Plus Optics, the discoscope described in the Richard Wolf YESS, the Endius Spine Endoscope, and the Pollux Arthroscope as demonstrated in Table 1.

TABLE 1
Substantial Equivalence Comparison Chart

Attribute	Joimax Endoscope	Richard Wolf Discoscope/YESS	Endius Spine Endoscope	Pollux Arthroscope
General Product Construction	Consists of rigid rod-lens, working channel, two (2) irrigation channels with stopcocks	Consists of rigid rod-lens, working channel, two (2) irrigation channels with stopcocks	Consists of a single rigid rod-lens.	Consists of rigid rod-lens, working channel, two (2) irrigation channels with stopcocks
Labeling	Non-sterile, Re-usable	Non-sterile, Re-usable	Non-sterile, Re-usable	Non-sterile, Re-usable
Used Materials	- Fiber optics for light transmission - Rigid rod-lens for image transmission - Stainless steel for endoscope housing	- Fiber optics for light transmission - Rigid rod-lens for image transmission - Stainless steel for endoscope housing	- Fiber optics for light transmission - Rigid rod-lens for image transmission - Stainless steel for endoscope housing	- Fiber optics for light transmission - Rigid rod-lens for image transmission - Stainless steel for endoscope housing
Intended Use	to visualize the inside of the patient through a cannulated incision for diagnostic and surgical procedures, such as arthroplasty, nucleotomy, discectomy, and foraminotomy.	- to visualize the inside of the patient via natural or surgically generated access. - for visualization and removal of herniated discs in the lumbar region.	- for use in viewing the lumbar disc through a cannulated incision to the interlaminar space of the involved disc level. - for posterior endoscopic access to the lumbar spine for various endoscopic spinal procedures such as discectomy and nucleotomy.	to visualize the interior of these particular joints which are the knee, shoulder, wrist, and ankle for arthroscopic procedures.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 1 2 2005

Joimax GmbH
c/o Mr. Morten Simon Christensen
Underwriters Laboratories, Inc.
1655 Scott Boulevard
Santa Clara, California 95050

Re: K051827
Trade/Device Name: THESSYS Multiscope
Regulation Number: 21 CFR 888.1100
Regulation Name: Arthroscope
Regulatory Class: II
Product Code: HRX
Dated: August 2, 2005
Received: August 3, 2005

Dear Mr. Christensen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Barbara Melkerson

for

Mark N. Melkerson
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K051827

Device Name: THESSYS Multiscope

Indications for Use:

The THESSYS Multiscope is intended to visualize the inside of the patient through a cannulated incision for diagnostic and surgical procedures, such as arthroplasty, nucleotomy, discectomy, and foraminotomy.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Barbara Bucknell for Melkerson

(Division Sign-Off)

Division of General, Restorative, and Neurological Devices

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